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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,832	01/11/2001	Joseph A. Horton	MCRVT-023C	8538
33197	7590	12/15/2004		
STOUT, UXA, BUYAN & MULLINS LLP 4 VENTURE, SUITE 300 IRVINE, CA 92618			EXAMINER THALER, MICHAEL H	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,832

Applicant(s)

HORTON ET AL.

Examiner

Michael Thaler

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 147,148,150-156,158,159 and 162-165 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 147,148,150-156,158,159 and 162-165 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3731

The disclosure is objected to because of the following informalities: It is unclear how the "ball 76" and "claw 78", described on page 33 lines 8-9 of the specification, acts to cut the strand. In claim 156, line 5, "in to" should be "into". Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP 608.01(o). Correction of the following is required: The claimed term "advancer" should appear in the specification in reference to the elected species, i.e., the species of the apparatus for delivering an electrical discharge. Also, the claimed term "embolus member" should appear in the specification or the claims should be amended to include the term "thrombogenic device" in place of "embolus member", noting that "thrombogenic device" is used in the specification on page 18, line 11.

The amendment filed Oct. 21, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the phrase "the claw 78 is on the distal end of an advancer" in the paragraph on page 33 beginning at line 6. Although the

Art Unit: 3731

original disclosure indicates that a ball and claw are used (page 33, lines 8-9), the original disclosure is silent as to whether the claw is on the advancer or the IFM and whether the ball is on the IFM or the advancer. Applicant is required to cancel the new matter in the reply to this Office Action.

Upon reconsideration, the new drawing figure 11 filed Sep. 26, 2003 is not approved since it contains new matter. New figure 11 shows the claw 78 on the advancer which is not disclosed in the original disclosure as indicated above.

Claims 148, 156, 158, 159, 162 and 165 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 148, line 9, there is no antecedent basis for "the third catheter". In claim 156, lines 7-8 are confusing since the text indicates that the strand has a collapsed configuration when it is positionable (i.e. not yet positioned) within the delivery catheter. In claim 158, line 1, "Claim wherein" is not understood.

Claim 164 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

Art Unit: 3731

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the original disclosure for the method step of retracting the intravascular member back to its collapsed configuration within the catheter after the intravascular member has been advanced out of the catheter and deployed in its expanded configuration. Although the original specification, on page 13, lines 16-18, indicates that the strand may be pulled back into the catheter "prior to full deployment", it nowhere indicates that the strand is pulled back into the catheter after the intravascular member has been advanced out of the catheter and deployed in its expanded configuration. For example, the text in the specification may mean that the strand may be pulled back into the catheter only after part of the intravascular member is outside of the catheter and part is still within the catheter, i.e. a situation in which it has not yet been "advanced out of the catheter and deployed in its expanded configuration".

Claims 147, 148, 150-156, 158, 159, 162, 163 and 165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limon (5,476,505) in view of Massoud et al. ("Endovascular Treatment of Fusiform Aneurysms with Stents and Coils: Technical Feasibility in a Swine Model"). Limon discloses delivery

Art Unit: 3731

catheter 34, intravascular member 10 that assumes a collapsed configuration when positioned within the delivery catheter (since it is within distal end opening 44 of catheter 34 as described in col. 4, lines 1-6) and advancer 32, which advances intravascular member 10 laterally out of the distal end opening 44 of delivery catheter as described in col. 4, lines 51-60, the intravascular member 10 being connected to advancer 32 by way of a releasable connection (at aperture 42), the releasable connection being volitionally releasable without requiring rotation of the advancer (The releasable connection at 42 is inherently volitionally releasable by rotating delivery catheter 34 while keeping advancer 32 stationary.), the intravascular member 10 being in the form of an elongate strand when in its collapsed condition (It is still an elongate strand even though the elongate stand has a helical shape when it is in its collapsed condition.), said elongate strand assuming a generally tubular shape having a hollow flow channel therethrough when the intravascular member is in its expanded configuration (figure 2). Limon fail to disclose retaining an embolus member within a vessel wall defect by the intravascular member. However, Massoud et al. teach that an embolus member may be so retained (the paragraph under the heading "Purpose" on page 1953 and the paragraph under the heading "Aneurysm Treatment" on page 1955)

Art Unit: 3731

apparently in order to occlude the vessel wall defect (aneurysm). It would have been obvious to make the vessel wall defect of Limon an aneurysm, insert an embolus member within the vessel wall defect and retain it by the intravascular member so that it is positively retained therein in view of this teaching in Massoud et al. As to claim 148, Limon fails to disclose a plurality of catheters. However, Massoud et al., in the paragraph labeled "Aneurysm Treatment" on page 1955, teach that a first catheter (the angiographic sheath), a second catheter (the guiding catheter) and a third catheter (the microcatheter) should be used to deploy a implantable device (the platinum coils) within a blood vessel. This arrangement has the apparent advantage of guiding the implantable device through narrow and tortuous blood vessels. Using first, second and third catheters to deploy the Limon intravascular member in order to obtain this advantage would have been obvious. As to claim 156, lines 15-17, blood flows through the flow channel in intravascular member 10 while it remains connected to advancer apparatus 32 as indicated in col. 4, lines 57-62. As to claim 162, the releasable connection is inherently releasable in response to electrical current, as broadly claimed, since the delivery catheter may be rotated by and electric motor, for example. As to claims 163 and 165, the intravascular member is inherently

Art Unit: 3731

capable of being retracted back into its collapsed configuration within the catheter after it has been advanced out of the catheter and deployed when the stent ends are loosely held within the slots 42, 44 as indicated in col. 4, lines 57-60 and the catheter 34 is then rotated in the opposite direction to retract the stent back to its collapsed configuration. Alternatively, the intravascular member is inherently capable of being retracted back into its collapsed configuration within the catheter after it has been advanced out of the catheter and deployed in the situation as follows: After the intravascular member has been completely deployed and the catheter 34 removed from the patient, the intravascular member is inherently capable of being removed from the patient by a stent remover and then put back into the same catheter 34 outside of the patient.

Claim 164 is free of any rejection based upon the prior art of record.

Applicant's arguments filed June 15, 2004 as well as the declaration of Jay Alan Lenker, Ph.D. have been fully considered but they are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

Art Unit: 3731

action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
12/10/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731